SEP 2 6 2008

510(k) Summary K081625

Date Prepared	September 26, 2008
Submitted by	VasoNova, Inc. 1368 Bordeaux Drive, Ste 100 Sunnyvale, CA 94089
Contact	Sorin Grunwald, Ph.D., MBA, Chief Technology Officer
Proprietary Name	FlowPICC™ Stylet, name subject to change
Classification	870.1200 Class II/880.5970 Class II
Predicates	ComboMap (Volcano K041134 SE 6/2/04) Sherlock (Bard K063240 SE 11/21/06)

Device Description

The FlowPICC™ System consists of a Console and a Stylet and is designed to be used with any commercially available PICC (peripherally inserted central catheter) with a minimum luminal diameter of 0.021 inches. The FlowPICC Stylet is a polymeric tube which contains a Doppler sensor and in intravascular electrocardiogram (ivECG) signal sensing wire. The Doppler sensor and the exposed portion of the ivECG signal sensing wire are located at the tip of the FlowPICC Stylet. The FlowPICC Stylet is 6 feet long and has an outer diameter of 0.019". The tip of the FlowPICC Stylet is positioned within a compatible catheter (luminal diameter 0.021") and maintained there throughout the PICC placement procedure. The proximal end has two connectors provide the connectivity to the FlowPICC Console.

Intended Use

The FlowPICC System, consisting of a Stylet and a Console, is indicated for use as a supplemental aid in PICC placement in patients requiring a PICC catheter. The FlowPICC™ Console when connected to the FlowPICC Stylet is intended for use with commercially available PICC catheters with minimum luminal diameter of 0.021" for assistance in tip placement of the PICC catheter in the patient's vasculature. The FlowPICC System provides real-time catheter tip location information by using the patient's physiological (cardiac electrical activity and blood flow) information. The Stylet provides stiffness for use in placement of the catheter, intravascular capability for ECG detection and recording, and intravascular ultrasound for catheter guiding and positioning.

Performance Data
Performance test results support the performance characteristics of the device and support substantial equivalence to the currently marketed predicate devices.

Conclusion
The FlowPICC Stylet has the same intended use and utilizes the same fundamental scientific technology as that of the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 6 2008

VasoNova, Inc.
c/o Sorin Grunwald, PhD, MBA
Chief Technology Officer
1368 Bordeaux Drive, Ste. 100
Sunnyvale, CA 94089

Re: K081625
Trade/Device Name: FlowPICC™ Stylet
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ
Dated: August 29, 2008
Received: September 2, 2008

Dear Dr. Grunwald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or

any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Indications for Use

510(k) Number (if known): K081625

Device Name: FlowPICC Stylet

Indications for use:

The FlowPICC System, consisting of a Stylet and a Console, is indicated for use as a supplemental aid in PICC placement in patients requiring a PICC catheter. The FlowPICC™ Console when connected to the FlowPICC Stylet is intended for use with commercially available PICC catheters with minimum luminal diameter of 0.021" for assistance in tip placement of the PICC catheter in the patient's vasculature. The FlowPICC System provides real-time catheter tip location information by using the patient's physiological (cardiac electrical activity and blood flow) information. The Stylet provides stiffness for use in placement of the catheter, intravascular capability for ECG detection and recording, and intravascular ultrasound for catheter guiding and positioning.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K081625

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K081625